C. Remarks

Claims 1-12 are pending in the application. Applicants acknowledge with appreciation the withdrawal of the Jacobson reference in response to Paper No. 15. Claim 1 has been amended herein to recite a peptide derived from the alpha-fetoprotein having SEQ ID NO:6. Support for this amendment appears throughout the Specification, and at least on page 11, lines 15-16. Thus, no new matter has been added.

Examiner's Comments:

(1) Claims 1-3 and 5 remain rejected under § 102(a) as anticipated by Mesfin *et al.*, 2001 (**C8**);

(2) Claims 1-2 remain rejected under § 102(b) as anticipated by U.S. Patent No. 5,532,167 to Cantley *et al.*;

(3) Claims 1-4 remain rejected under § 102(e) as anticipated by U.S. Patent No. 6,348,567 to Krystal *et al.*; and

(4) Claims 6-8 are objected to as dependent upon a rejected base claim.

Applicants respond to each of the Examiner's comments, below.

Novelty

Rejection of Claims 1–3 and 5 under 35 U.S.C. §102(a)

Claims 1-3 and 5 stand rejected under 35 U.S.C. §102(a) as anticipated by Mesfin *et al.*, 2001 (C8 on the IDS, hereafter "Mesfin"). Applicants traverse for the following reasons.

Mesfin was published in March 2001, and was written by the joint inventors of the instant application. Mesfin discloses sequences EMTOVNOG (SEQ ID NO:4) and EMTOVNOGQ (SEQ ID NO:5), which are also the subject matter of claims 1-3 and 5. Applicants assert that these sequences were first invented by the present inventors prior to the March 2001 publication date of Mesfin. Applicants submit herein a declaration of Dr. Thomas Andersen attesting to the conception and reduction to practice of SEQ ID NOS: 4 and 5 prior to the publication of Mesfin. Since applicants have established that the subject matter of the present claims was invented prior to the publication date of Mesfin, Mesfin is not 102(a) prior art. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Rejection of Claims 1 and 2 under 35 U.S.C. §102(b)

Claims 1 and 2 remain rejected under 35 U.S.C. §102(b) as anticipated by Cantley *et al.* U.S. Patent No. 5,532,167. Specifically, the Examiner rejected claims 1 and 2 because Cantley discloses a sequence (SEQ ID NO:36) that allegedly reads on an analog of SEQ ID NO:6. The Examiner asserts that a *prima facie* case of anticipation has been made and cites MPEP 2112.01 in support of this assertion. While Applicants respectfully disagree with the Examiner's conclusion, as the products are from completely unrelated pathways, claim 1 has been amended herein for purposes of expediting prosecution.

Claim 1 now recites a peptide which is derived from, rather than an analog of, the alpha-fetoprotein having SEQ ID NO:6. SEQ ID NO: 36 disclosed by Cantley is a 9 residue fragment derived from the 1,833 amino acid sequence of the HIV Enhancer-Binding Protein 2 (HIV-EP2) and clearly does not possess antiestrotrophic activities (*see* courtesy copy of Nomura *et al.* (1991) enclosed herewith, at p. 8592, Fig. 2, line 1550 of the sequence). The HIV-EP2 protein has been characterized and was found to possess a DNA-binding domain containing a zinc-finger structure, a Ser/Thr-rich sequence, and a cluster of acidic amino acids (*see* Nomura, p. 8590, col. 2). Significantly, no part of the active domain encompasses the 9 residue fragment that is SEQ ID NO:36 in Cantley. Furthermore, a comparison of the levels of HIV-EP2 mRNA expressed in various cells indicates a high expression of the protein in T cells, as a regulatory component of T cell growth control (*see id.* and p. 8591, col. 1).

In stark contrast, AFP is a serum glycoprotein that is produced in the fetus and is involved in the decreased risk of breast cancer by inhibiting estrogen-stimulated growth of certain cancer cell lines, *i.e.*, possesses antiestrotrophic activity. Significantly, the peptides contemplated by the present invention retain such antiestrotrophic activity as they are derived from, and significantly similar to, that portion of the AFP responsible for its antiestrotrophic effects (SEQ ID NO:6). Accordingly, Applicants reassert that the peptides of claims 1 and 2 are not anticipated by SEQ ID NO:36 of Cantley because SEQ ID NO:36 lacks antiestrotrophic activity. Objective evidence supporting this assertion has been supplied in the form of the Nomura *et al.* reference characterizing the HIV-EP2 protein from which SEQ ID NO: 36 is derived. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 1-4 under 35 U.S.C. §102(e)

Claims 1-4 remain rejected under 35 U.S.C. §102(e) as anticipated by Krystal *et al.* U.S. Patent No. 6,348,567. Specifically, the Examiner rejects claims 1-4 because Krystal discloses a sequence (SEQ ID NO:5) that allegedly reads on an analog of SEQ ID NO:6. Applicants traverse the rejection as applied to the claims as amended for the reason set forth below.

Again, Applicants have amended claim 1 to expedite prosecution of this application. Claim 1 now reads a peptide derived from the alpha-fetoprotein of SEQ ID NO:6. Krystal discloses SEQ ID NO:5 which it is specifically stated is derived from a streptokinase enzyme (*see* Krystal, col. 4, lines 19-21). As such Krystal does not meet the limitations of claim 1 and cannot anticipate the invention recited therein.

Since claims 2-4 depend directly or indirectly from claim 1, and therefore incorporate all the limitations of claim 1, Krystal cannot anticipate these claims either.

Reconsideration and withdrawal of the rejections are respectfully requested.

Claim Objections

Objection to claims 6-8 Overcome

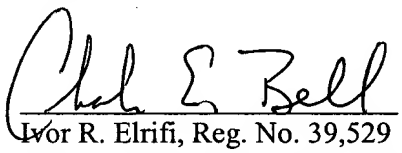
The Examiner objected to claims 6-8 for depending upon a rejected base claim. These objections stand or fall with the rejections of claims 1-5. In view of the arguments above, the remaining rejections to claims 1-5 have been overcome. Thus, the objections to claims 6-8 are moot and should be withdrawn.

Summary

On the basis of the foregoing remarks, Applicants respectfully submit that this paper is fully responsive, and that the pending claims are in condition for allowance. Such action is respectfully requested. If there are any questions regarding the content of this paper, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

This Response is being submitted within 3 months from the mailing of the Final Office Action, *i.e.*, November 25, 2003. No fees are believed due with this filing. However, the Commissioner is hereby authorized to charge payment of any fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 19705-010.

Respectfully submitted,



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